Data Evaluation Report on the effects of saflufenacil and dimethenamid-p on *Aphidius rhopalosiphi*

PMRA Submission Number: 2008-0432 **MRID#: 47523901**

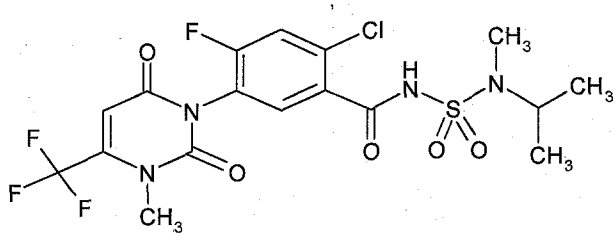
PMRA# for DER: 1636089 **PMRA# for original study: 1633866**

Data requirement

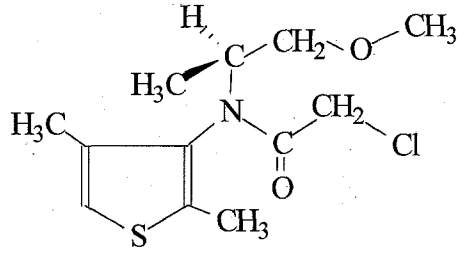
PMRA Data Code: 9.2.6
EPA DP Barcode: 349851
OECD Data Point: IIA 8.8.1.1
EPA Guideline: n/a
OPPTS Guideline: n/a

Test material: **BAS 781 02 H** **Guarantee:** 6.1% BAS 800 H (saflufenacil)
53.6% BAS 656 H (dimethenamid-p)

Active ingredient: saflufenacil
IUPAC: N'-[2-chloro-4-fluoro-5-(3-methyl-2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2H)-pyrimidinyl)benzoyl]-N-isopropyl-N-methylsulfamide
CAS name: 2-chloro-5[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2H)-pyrimidinyl]-4-fluoro-N-[(methyl(1-methylethyl)amino]sulfonyl]-benzamide
CAS No.: 372137-35-4
Synonyms: BAS 800 H
Structural formula:



Active ingredient: dimethenamid-p
IUPAC: (S)-2-chloro-N-(2,4-dimethyl-3-thienyl)-N-(2-methoxy-1-methoxy-1-methylethyl) acetic acid
CAS name: 2-chloro-N-(2,4-dimethyl-3-thienyl)-N-((1S)-2-methoxy-1-methylethyl) acetamide
CAS No.: 163515-14-8
Synonyms: BAS 656 H
Structural formula:



Primary Reviewer: Janine Glaser (1009) **Date:** 2008-Sep-16
Canada-HC-PMRA-EAD

Secondary Reviewers: Anita Pease **Date:** 2009-Jun-09
United States-EPA-OPP-EFED-ERB4

Apease
6/9/09

PMRA Company Code	BAZ
PMRA Active Code	SFF (saflufenacil), DMN (dimethenamid-p)
PMRA Use Site Category	13, 14
EPA PC Code	118203 (saflufenacil), 120051 (dimethenamid-p)

CITATION: Stevens J. 2008. A rate-response laboratory test to determine the effects of BAS 781 02 H on the parasitic wasp, *Aphidius rhopalosiphi* (Hymenoptera, Braconidae). 2008-Aug-26. BASF-2008/1036407; MRID-47523901; PMRA-1633866.

EXECUTIVE SUMMARY

The effects of the emulsifiable concentrate BAS 781 02 H (6.1% saflufenacil, 53.6% dimethenamid-p) on mortality of the parasitic wasp (*Aphidius rhopalosiphi*) were determined. Ten wasp imagines per replicate were exposed to dried residues on glass plates at rates of 1.889, 4.721, 11.803, 29.508, 73.770ml product/ha (0.1152, 0.288, 0.72, 1.8, and 4.5g saflufenacil/ha; 1.012, 2.531, 6.326, 15.816, and 39.541g dimethenamid-p/ha) over a period of 48 hours. In addition, purified water as control and a toxic reference (dimethoate, 400 g/l) at 0.10 mL product/ha were tested. The test was conducted with 4 replicates per rate. Mortality was used to determine the endpoint. The 48h LR50 value was 19ml product/ha (1.2g saflufenacil/ha; 10.3g dimethenamid-p/ha).

This study is classified as **FULLY RELIABLE** to PMRA and **SUPPLEMENTAL** to EPA (data are not required for registration in the USA). The results are suitable for use in regulatory risk assessment. However, a Tier 1 in-field risk assessment indicates that higher tier testing should have been conducted (the in-field RQ values exceed the level of concern (LOC 2.0), Table 1). A refined assessment considering the use pattern (pre-emergent application and pre-plant incorporation) assumes foliar interception of 0% and soil deposition of 100%. Therefore, testing on ground dwelling species should be conducted for a refined assessment (such as predatory ground beetle *Poecilus cupreus* or rove beetle *Aleochara bilineata* or spider *Pardosa*).

Table 1: Tier 1 risk assessment of emulsifiable concentrate BAS 781 02 H (6.1% saflufenacil, 53.6% dimethenamid-p) on *Aphidius rhopalosiphi*

Risk assessment parameter	Canada	USA
EEC	75 g saflufenacil/ha	0.24 lb saflufenacil/A
LR50	1.2 g saflufenacil/ha	0.0011 lb saflufenacil/A
RQ (EEC / LR50)	62	218

Results Synopsis

Test organism: *Aphidius rhopalosiphi* imagines
48h LR50: 19ml product/ha (1.2g saflufenacil/ha; 10.3g dimethenamid-p/ha)

% deviation from control
for reproductive endpoint: not determined

I. MATERIALS AND METHODS

Guideline: IOBC/OILB 2000 (Mead-Briggs et al., pp 13-25)
GLP: yes (certified laboratory)
Testing facility: Mambo-Tox Ltd, Chilworth Science Park, Southampton, UK
Dates of work: 2008-Jul-7 to 2008-Jul-18
Deviations: Test was performed without the reproduction phase

A. Test substance

Name: BAS 781 02 H
Type of formulation: EC (emulsifiable concentrate) formulation
Batch No.: 1632-78
Expiry date: 2009 Oct 5
Content: 6.2% saflufenacil, 54.6% dimethenamid-p (analysed)
Density: 1.0901 g/ml

Table 2: Physical and chemical properties of active substances

Parameter	Saflufenacil			Dimethenamid-p
Water solubility	pH 4 0.0014 g/100 mL pH 5 0.0025 g/100 mL pH 7 0.21 g/100 mL pH 9 not determined due to degradation			1449 ± 17 mg/l at 25°C
Vapour pressure	4.5×10^{-15} Pa at 20°C 2.0×10^{-14} Pa at 25°C			1.88×10^{-5} mm Hg at 25°C
UV absorption	pH λ_{max} (nm) ε (L/mol-cm)	1.12 271.8 9539	6.94 271.4 9708	λ_{max} 236 nm at pH <2, 7 & >10. No absorption at 300-750 nm.
pK_a	4.41			No dissociable groups present
log K_{ow}	2.6			1.89

B. Toxic reference

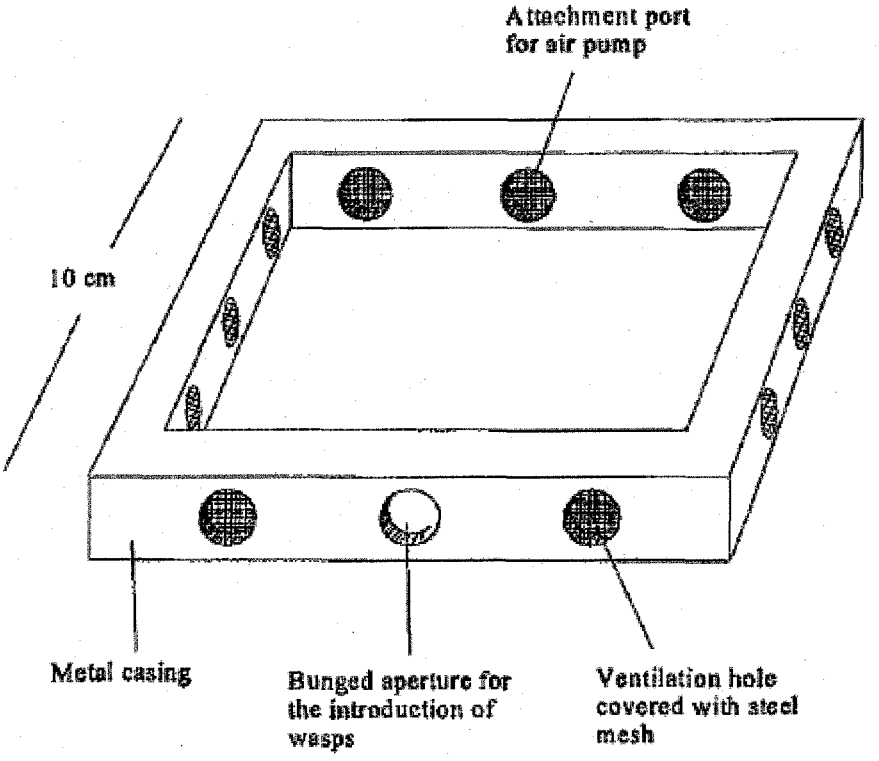
Identification code: BAS 152 11 I
Active ingredient: Dimethoate
Analysed content: 395.9 g/l
Type of formulation: emulsifiable concentrate

C. Test organisms

Species: *Aphidius rhopalosiphi*
Common name: parasitic wasp
Age: imagines, <48 hours after emergence
Source: Katz Biotech AG, Baruth, Germany;
formerly P.K Nützlingszuchten, Welzheim, Germany

D. Design of biological test

Ten imagines were exposed to dried residues of BAS 781 02 H in a standard laboratory test in a 2-dimensional test system on glass plates over a period of 48 hours. The test item was applied at rates of 1.889, 4.721, 11.803, 29.508, 73.770ml product/ha (0.1152, 0.288, 0.72, 1.8, and 4.5g saflufenacil/ha; 1.012, 2.531, 6.326, 15.816, and 39.541g dimethenamid-p/ha) with a water volume of 200 L/ha. In addition, purified water as control and a toxic reference (dimethoate, 400 g/l) at 0.10 mL product/ha were tested. One unit consisted of two treated glass plates (100×100mm) fitted to the top and bottom of a square metal frame (inner size 95×95×18mm) with three ventilation holes on each side. This set-up served as one exposure unit (replicate) in which 10 imagines were released at test start. The test was conducted with 4 replicates per rate. The food provided to the wasps was a piece of cotton wool soaked in 1:3 v/v mixture of honey and water. The cotton wool would have been remoistened daily; however, this was not specified in the original report.



D. Observations and measurements

Mortality (including moribund insects) was assessed at 2, 24, and 48 hours after introduction to test units. Affected insects (upright, attempting to walk but with reduced coordination or inactive) were also recorded at the same times. Light intensity was measured once at the beginning of the test. The temperature and relative humidity were measured each hour.

II. RESULTS

A. Physical and chemical parameters

Test temperature: 20°C
Relative air humidity: 60-87%
Photoperiod: 16 hours light/ 8 hours dark
Light intensity: 1850 lux

B. Verification of the application volume

The sprayer was calibrated in advance of treatment by weighing spray deposits until two consecutive applications had delivered 200 L/ha (2 mg deposit/cm^2).

C. Biological findings

Effects are listed as follows:

Table 3: Effects of BAS 781 02 H on *Aphidius rhopalosiphi* after 48 hours

Treatment	ml product/ha	% affected	% mean mortality (uncorr.)	% mean mortality (corr.)
control	0.000	0.0	0.0	—
Test item	1.889	0.0	0.0	0.0
Test item	4.721	0.0	2.5	2.5
Test item	11.803	2.5	2.5	2.5
Test item	29.508	10.0	87.5*[a]	87.5
Test item	73.770	0.0	100.0*	100.0
Reference item	0.10 mL product/ha	0.0	100.0*	100.0

*statistically different to the control (Fisher's Exact Test, α=0.05)
[a]study author reported mean mortality as 90.0%; however, Regulatory Authority calculated it to be 87.5 (35/40 individuals)

Statistical analysis of trial results to detect significant differences was not verified by the Regulatory Authority since they are not used to determine the key regulatory endpoint.

D. Test with toxic reference substance

The reference item was dimethoate (395.9 g/l analysed) and was applied under the same test conditions at 0.1 mL/ha (4 replicates). The cumulative mean mortality of mites exposed to the reference item after 48 hours was within the expected limits of 50-100% (M_{corr} = 100.0%). Thus, the test with toxic reference substance demonstrates the sensitivity of the test system.

E. Validity criteria

The validity criterion of 48h control mortality ≤13% is fulfilled. The validity criterion regarding the performance of the toxic reference is fulfilled.

F. Biological endpoints derived

From the results presented above, the following biological endpoint was derived by the study author:

7d LR50: 19ml product/ha (1.2g saflufenacil/ha; 10.3g dimethenamid-p/ha)

95% CI: not reported
Analysis: Probit regression

Regression coefficent: 5.596 (SE 0.247)
Intercept of probit line: -0.380 (SE 0.059)
Goodness of fit (χ^2): 3073 with 18 d.f. ($p<0.001$)

The derived endpoint was verified by the Regulatory Authority by plotting the probit of mean corrected mortality versus log concentration in SigmaPlot; therefore, the endpoint derived from the study author is acceptable and was retained.

Regulatory Authority analyses:

Probit of corrected replicate mortality versus log concentration
$y = 1.1300 + 3.2085x$ (r^2 0.83)
LR50 16ml product/ha

Probit of corrected mean mortality versus log concentration
Forced through origin
$y = -0.2464 + 4.1136$ (r^2 0.71)
LR50 19ml product/ha

To convert the test rates and LR50 value to a.i.-equivalent rates, the study author used nominal content values and a product density of 1 g/ml. Using measured content values and measured product density of 1.09 g/ml does not significantly alter the a.i.-equivalent LR50 values. Therefore, the saflufenacil equivalent LR50 reported by the study author was retained, and the Regulatory Authority used the same method to obtain the dimethenamid-p-equivalent LR50.

III. STUDY DEFICIENCIES

Effects on reproduction were not determined. However, a Tier 1 in-field risk assessment indicates that higher tier testing should have been conducted (the in-field RQ values exceed the level of concern (LOC 2.0), Table 4). A refined assessment considering the use pattern (pre-emergent application and pre-plant incorporation) assumes foliar interception of 0% and soil deposition of 100%. Therefore, testing on ground dwelling species should be conducted for a refined assessment (such as predatory ground beetle *Poecilus cupreus* or rove beetle *Aleochara bilineata* or spider *Pardosa*).

Table 4: Tier 1 risk assessment of emulsifiable concentrate BAS 781 02 H (6.1% saflufenacil, 53.6% dimethenamid-p) on *Aphidius rhopalosiphi*

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LR50	1.2 g saflufenacil/ha	0.0011 lb saflufenacil/A
RQ (EEC / LR50)	62	218

V. CONCLUSIONS

This study is classified as **FULLY RELIABLE** to PMRA and **SUPPLEMENTAL** to EPA (data are not required for registration in the USA). The study appears to have been well conducted and reported. The results are suitable for use in regulatory risk assessment. The 48h LR50 value was 19ml product/ha (1.2g saflufenacil/ha; 10.3g dimethenamid-p/ha).

A Tier 1 in-field risk assessment indicates that higher tier testing should have been conducted (the in-field RQ values exceed the level of concern (LOC 2.0), Table 4). A refined assessment considering the use pattern (pre-emergent application and pre-plant incorporation) assumes foliar interception of 0% and soil deposition of 100%. Therefore, testing on ground dwelling species should be conducted for a refined assessment (such as predatory ground beetle *Poecilus cupreus* or rove beetle *Aleochara bilineata* or spider *Pardosa*).